

Appln. No. 09/742,033

Amdt. dated November 24, 2003

Response to Final Office Action of May 30, 2003

REMARKS

Claims 3, 4, 9-20, 22 and 26-34 were pending in this application.

Claims 23-25 were previously withdrawn from further consideration by the Examiner pursuant to 37 C.F.R. § 1.142(b) as being drawn to non-elected inventions, and are hereby canceled without prejudice.

Claim 22 is hereby canceled without prejudice.

Amendments were made to Claims 3, 4, and 14 to more particularly point out and distinctly define the invention. Support for these amendments is found throughout the specification and examples as filed (*e.g.*, p. 9, line 15 through p. 15, line 5; Example 1; Figure 1 and associated text).

Finally, new Claims 35-40 have been added to further define the invention. Support for these new claims is found throughout the specification and examples as filed (*e.g.*, p. 9, line 15 through p. 15, line 5; Example 1; Figure 1 and associated text).

No new matter is contained either in the amendments or the new claims. Accordingly, reconsideration and withdrawal of the rejections of the application is respectfully requested in view of the amendments and remarks herein.

I. Finality Of Rejection Is Improper And Should Be Reversed.

Applicants respectfully submit that the finality of the rejection is improper because new rejections are set forth in the Office Action that were not previously made and were not necessitated by amendments to the claims.

As set forth in the MPEP:

Under present practice, second or any subsequent actions on the merits shall be final, except where the examiner introduces a new ground of

Appln. No. 09/742,033

Amdt. dated November 24, 2003

Response to Final Office Action of May 30, 2003

rejection that is neither necessitated by applicant's amendment of the claims nor based on information submitted in an information disclosure statement filed during the period set forth in 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p).... Furthermore, a second or any subsequent action on the merits in any application or patent undergoing reexamination proceedings will not be made final if it includes a rejection, or newly cited art, other than information submitted in an information disclosure statement filed under 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p), of any claim not amended by applicant or patent owner in spite of the fact that other claims may have been amended to require newly cited art.

(MPEP § 706.07(a)).

More specifically, paragraph 37 of the Office Action introduces newly cited art, Knight et al. (Knight, A.W.; Greenway, G.M. "Relationship Between Structural Attributes and Observed Electrogenated Chemiluminescence (ECL) Activity of Tertiary Amines as Potential Analytes for the Tris(2,2-Bipyridine)Ruthenium(II) ECL Reaction" *Analyst* 1996, 121, 101R-106R) (hereinafter "Knight II"). The fact that the new rejection based on Knight II was not necessitated by Applicants' amendments is made clear by the Examiner's use of the reference in a rejection of Claim 9, a claim to a specific compound whose scope was unaffected by any amendment to the claim. Applicants, therefore, urge that the finality of the present Office Action is improper.

Furthermore, the MPEP also emphasizes the importance of reaching a clearly defined issue between the Applicants and the Examiner prior to issuance of a final office action:

Before final rejection is in order a clear issue should be developed between the examiner and applicant.... the goal of reaching a clearly defined issue for an early termination, i.e., either an allowance of the application or a final rejection.

The examiner should never lose sight of the fact that in every case the applicant is entitled to a full and fair hearing, and that a clear issue between applicant and examiner should be developed, if possible, before appeal.

(MPEP § 706.07).

Appln. No. 09/742,033

Amdt. dated November 24, 2003

Response to Final Office Action of May 30, 2003

Thus, Applicants believe it is improper to make an office action final when Applicants did not have an opportunity to distinguish the newly cited art from the disclosure in the subject specification and to fully rebut the Examiner's arguments.

Therefore, Applicants respectfully request that the finality of the Office Action be removed.

II. Status Of The Claims

Although Applicants do not agree with the Examiner's reasons for restricting Claims 23-25, Applicants are herewith canceling Claims 23-25 without prejudice for prosecution in a divisional application.

Claims 3, 4, 9-20, 22, 26-34 were pending in this application. With this Amendment, Claim 22 has been canceled without prejudice, Claims 3, 4 and 14 have been amended to more clearly define the chemical properties of the coreactant, and Claims 35-40 have been added to more clearly define the invention. Thus, Claims 3, 4, 9-20, and 26-40 are currently pending.

Applicants take this opportunity to thank the Examiner for withdrawing his: (1) objection to Figure 1 and to the oath and/or declaration; (2) description and enablement rejections to Claim 9 under 35 USC § 112, first paragraph; and (3) rejection under 35 USC § 102(g) over U.S. Patent No. 5,591,581 to Massey et al.

The following issues (other than the priority of claims issue addressed in Section III below) remain from the Office Action:

- a) Claims 3, 4, 10-20, 22 and 26-34 are rejected under 35 USC § 112, first paragraph (written description requirement);

Appln. No. 09/742,033

Amdt. dated November 24, 2003

Response to Final Office Action of May 30, 2003

- b) Claims 3, 4, 10-20, 22 and 26-34 are rejected under 35 USC § 112, first paragraph (enablement requirement);
- c) Claims 3, 4, 9-20, 22 and 26-34 are rejected under 35 USC § 112, second paragraph (definiteness requirement);
- d) Claims 3-4, 10, 12-13, 18-20, 22, 26-27 and 29-34 are rejected under 35 USC § 102(a) as purportedly being anticipated by Liang et al. (Liang, P.; Dong, L., Martin, M.T. "Light Emission from Ruthenium-Labeled Penicillins Signaling Their Hydrolysis by β -Lactamase" *J. Am. Chem. Soc.* 1996, *118*, 9198-9199) (hereinafter "Liang");
- e) Claims 3, 11, 13, 14 and 31-34 are rejected under 35 USC § 102(b) as purportedly being anticipated by Faulkner (Faulkner L.R. "Chemiluminescence from Electron-Transfer Processes" *Methods in Enzymology* (ed. by Marlene A. Deluca) 1978, *17*, 494-526) (hereinafter "Faulkner");
- f) Claims 3-4, 10-14, 19-20, 22, 26-27 and 29-34 are rejected under 35 USC § 102(b) as purportedly being anticipated by Massey et al. (WO 87/06706);
- g) Claims 3-4, 10-14, 19-20, 22, 26-27 and 29-34 are rejected under 35 USC § 102(e) as purportedly being anticipated by Massey et al. (U.S. Patent No. 5,591,581) (the "Massey '581 patent");
- h) Claims 3-4, 10-14, 19-20, 22, 26-27 and 29-34 are rejected under 35 USC § 102(f) as purportedly being anticipated by the Massey '581 patent;

Appln. No. 09/742,033

Amdt. dated November 24, 2003

Response to Final Office Action of May 30, 2003

- i) Claims 3-4, 9-20, 22 and 26-34 are rejected under 35 USC § 103(a) as purportedly being obvious over Knight et al. (Knight, A.W.; Greenway, G.M. "Occurrence, Mechanisms and Analytical Applications of Electrogenenerated Chemiluminescence" *Analyst* 1994, 119, 879-890) (hereinafter "Knight I") in view of Faulkner;
- j) Claims 3-4, 9-20, 22 and 26-34 are rejected under the judicially created doctrine of obviousness-type double patenting over claims 1-6 and 19-20 of the Massey '581 patent and over claims 1-6 of Liang et al. (U.S. Patent No. 5,643,713¹);
- k) Claims 3-4, 9-20, 22 and 26-34 are rejected under 35 USC § 101 as purportedly being directed to non-statutory subject matter;
- l) Claims 3-4, 9-20, 22 and 26-34 are rejected under 35 USC § 112, first paragraph (new matter rejection); and
- m) Claims 3-4, 9-20, 22 and 26-34 are rejected under 35 USC § 103(a) as purportedly being obvious over Knight II in view of Faulkner.

Applicants respectfully traverse each of the above-identified rejections for the reasons set forth below.

¹ Applicants note that in paragraph 30 of the Office Action the Examiner refers to Nakagawa et al. (U.S. Patent No. 6,643,713) instead of Liang et al. (U.S. Patent No. 5,643,713). Since the Nakagawa '713 patent for "Apparatus Has a Microprocessor Including DSP and a CPU Integrated with Each Other as a Single Bus Master" has nothing to do with electrochemiluminescence, reference to that patent is obviously a typographical error.

Appln. No. 09/742,033

Amdt. dated November 24, 2003

Response to Final Office Action of May 30, 2003

III. Priority Of Claims.

Applicants submit that Claims 9, 11 and 14-16 are supported by parent case U.S.S.N. 08/936,971 and have a priority date no later than September 25, 1997. Claims 3-4, 10-13, 17-20, 22, and 26-34 are fully supported by the disclosure of U.S.S.N. 08/484,766 (“the ‘766 application”) and have a priority date no later than June 7, 1995.

The ‘766 priority application discloses and therefore provides complete support for the broad genus of compounds claimed in Claims 3-4, 10-13, 17-20, 22² and 26-34 of the subject application. Although the ‘766 priority application does not delineate the particular species of Claims 9, 11 and 14-16, which belong to the disclosed genus, the lack of disclosure of particular species does **not** negate the full support provided for the detailed description of the claimed genus. *See Heymes v. Takaya*, 6 USPQ2d 1448, 1452 (BPAI 1988).

Consequently, contrary to the Examiner’s assertion, the generic claims are fully supported by the disclosure in the ‘766 priority application.

IV. Response To Specific Rejections**A. Claims 3, 4, 10-20, And 26-34 Satisfy The Written Description Requirement.**

The Examiner asserts that Claims 3, 4, 10-20 and 26-34 contain subject matter which purportedly “was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.” (Office Action, p. 5, ¶ 8). More specifically, the Examiner argues:

² Applicants note that they have canceled Claim 22 by this Amendment for reasons unrelated to patentability, therefore, this issue and all other issues raised for this claim are moot.

Appln. No. 09/742,033

Amdt. dated November 24, 2003

Response to Final Office Action of May 30, 2003

... applicants have not provided enough examples to demonstrate that they are in possession of the full scope of the invention as claimed. For example, it is not possible to know which ECL/CR pairs will have sufficient energy and react with sufficient speed [...] to produce the necessary electronically excited products.... For example, applicants' claims would also encompass energy-deficient systems that generate light emission via triplet-triplet annihilation.... *et seq.*

(Office Action, pp. 5-6, ¶ 8).

Applicants respectfully traverse for the reasons presented below.

1. The Scope of the Disclosure Is
 Commensurate with the Scope of the Claims.

Applicants submit that the function of the written description requirement is to ensure that a patent is granted to inventors who had possession, as of the filing date of the application relied upon, of the specific subject matter later claimed by them; how the specification accomplishes this is not material. *In re Smith*, 178 USPQ 620, 623-24 (CCPA 1973). Therefore, the test for written description under 35 U.S.C. §112, first paragraph, is whether the originally filed specification reasonably conveys to a person having ordinary skill that Applicants had possession of the subject matter later claimed. *In re Kaslow*, 217 USPQ 1089, 1096 (Fed. Cir. 1983). (*See also*, MPEP § 2163.02).

Applicants respectfully submit that there is no reasonable basis for asserting that the claims must be limited to the specific species disclosed in the specification. The original specification broadly describes the terms “electrochemiluminescent label” and “coreactant” (*see* Specification, pp. 6 and 9) and discloses an extensive list of useful pairs and linkers (*see* Specification, p. 16, line 23 -p. 18, line 2).

Appln. No. 09/742,033

Amdt. dated November 24, 2003

Response to Final Office Action of May 30, 2003

2. The Patent Need Not Describe What Is Well Known in the Art.

The invention is ECL labels linked to ECL coreactants. Applicants discovered that ECL can be more efficiently induced by linking these species rather than by using them as separate components in a mixture. ECL labels, ECL coreactants and linking groups for linking two chemical moieties together were all well known in the art. Thus, the skilled practitioner would be aware of numerous classes of each of these components as well as the structural features responsible for their activity. Given the level of skill in the art, the recitation of an ECL label linked to a coreactant is sufficient to permit a person skilled in the art to recognize that Applicants were in possession of the claimed invention.

3. Examples Are Not Required to Meet the Written Description Requirement.

Examples are not required to meet the written description requirement. As set forth in MPEP § 2163:

The first paragraph of 35 U.S.C. 112 requires that the ‘specification shall contain a written description of the invention * * *.’ This requirement is separate and distinct from the enablement requirement. See, e.g., *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1560, 19 USPQ2d 1111, 1114 (Fed. Cir. 1991)....

* * *

An applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams, and formulas that fully set forth the claimed invention. *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997). Possession may be shown in a variety of ways including description of an actual reduction to practice, or by showing that the invention was ‘ready for patenting’ such as by the disclosure of drawings or structural chemical formulas that show that the invention was complete, or by describing distinguishing identifying characteristics sufficient to show that the applicant was in possession of the claimed invention. See, e.g., *Pfaff v. Wells Elecs., Inc.*, 525 U.S. 55, 68, 119 S.Ct. 304, 312, 48 USPQ2d 1641, 1647 (1998); *Eli Lilly*, 119 F.3d at 1568, 43 USPQ2d at 1406; *Amgen, Inc. v. Chugai*

Appln. No. 09/742,033

Amdt. dated November 24, 2003

Response to Final Office Action of May 30, 2003

Pharmaceutical, 927 F.2d 1200, 1206, 18 USPQ2d 1016, 1021 (Fed. Cir. 1991) (one must define a compound by ‘whatever characteristics sufficiently distinguish it’).

(MPEP § 2163 at 2100-159).

The presently claimed subject matter is described in the original specification (*i.e.*, Specification, pp. 8-25; Examples 1-4; Figures 1 and 2). Thus, it is unclear what the basis is for this aspect of the Examiner’s “written description” objection.

4. In Any Event, the Specification Provides Examples of Suitable Compounds as Well as Detailed Lists of Suitable Components (*i.e.*, ECL Labels, ECL Coreactants and Linkers).

The specification lists numerous suitable ECL labels (*see* Specification, pp. 22-25). Detailed descriptions of a variety of ECL labels are also given in references incorporated in the specification. (*See* Specification, p. 3, lines 16-25). For example, the specification incorporates by reference a number of patents which reflect certain applications of ECL (*see* Specification, p. 3, lines 16-21), as well as scientific references (*see* Specification, p. 4, lines 1-5).

Moreover, the specification explicitly lists coreactants and references appropriate literature:

Some examples of known CR species include amines, peroxides, persulfates, oxalates and cofactors (e.g. NADH). Other Examples are known in the art; for example; see the previously described references...

(Specification, p. 10, lines 5-8).

The specification elaborates further on the preferred embodiments of coreactants throughout the application and gives specific structural details of the preferred coreactants (*see* Specification, p. 13, line 11 - p. 15, line 5), e.g., “Amines which are advantageously utilized in the present invention are aliphatic amines, such as [...]” (Specification, p. 13, lines 11-12) and

Appln. No. 09/742,033

Amdt. dated November 24, 2003

Response to Final Office Action of May 30, 2003

“other suitable [...] are oxalate or other organic acid radicals such as pyruvate, lactate, tartrate, and citrate” (Specification, p. 15, lines 1-3).

Furthermore, Claims 3 and 4, as amended, specify that suitable coreactants must have the chemical property that they can be “oxidized to form a reductant or reduced to form an oxidant.” This chemical property defines a narrow subgenus of compounds and an artisan skilled in the art of electrochemistry would readily recognize which compounds belong to this subgenus, or would know how to determine which compounds belong to the claimed subgenus.

In addition, the specification describes a variety of suitable linkers and linking chemistries for linking the ECL label and ECL coreactant: “Examples of appropriate linking groups include NHS-esters, carboxylic acids, amines, thiols, disulfides, maleimide, hydroxyl and the like; these and other functional groups that can be used to attach biomolecules are, in and of themselves, well known in the art” (*see* Specification, p. 17, lines 18-22). The wide varieties of linkers, which utilize standard chemistry, were readily available to a skilled artisan from commercial companies at the time the present application was filed. Suitable linkers that are explicitly described include “a polymer, a polypeptide chain, a polynucleic acid strand, a polysaccharide, an oligo-ethylene glycol group, a fiber or the like” (*see* Specification, p. 17, lines 24-26).

5. Many of the Rejected Claims Explicitly Recite Structural Features.

While Applicants disagree with the Examiner’s rejection of their broadest claim recitations under 35 USC § 112, first paragraph for purportedly not explicitly reciting structural features, Applicants direct the Examiner’s attention to several rejected claims that do explicitly recite structural features. Claims 13-18 recite specific structural features of the coreactant.

Appln. No. 09/742,033

Amdt. dated November 24, 2003

Response to Final Office Action of May 30, 2003

Claims 19 and 26 recite specific structural features of the label. Claims 20 and 28-29 list specific structural features of the linker. Newly added dependent Claims 35-40 recite specific structural features of both the label and coreactant. Given the high level of skill in the art of using amines (and especially tertiary amines) as ECL coreactants and metal complexes (and especially metal complexes of ruthenium and osmium) as ECL labels, the level of description is more than sufficient to show that the Applicants were in possession of the claimed inventions. Thus, there is no reasonable basis to assert that the present claims must be limited to the specific compounds disclosed as examples in the present specification in order to comply with the first paragraph of 35 USC § 112.

6. One Skilled in the Art Would Understand the Inventors
to be in Possession of the Claimed Invention
Despite Existence of the Possibility of “Energy-
Deficient” Systems Based on Triplet-Triplet Annihilation.

Applicants urge that whether electrochemiluminescence occurs via singlet relaxation or via triplet-triplet annihilation is immaterial to the patentability of the claimed subject matter. The specification provides an empirical definition of what Applicants regard as electrochemiluminescence:

In electrochemiluminescence, the electronically excited state is generated upon exposure of the molecule (or a precursor molecule) to electrochemical energy in an appropriate surrounding chemical environment.

(Specification, p. 2, line 25 - p. 3, line 3).

In both the relaxation or annihilation mechanisms, the reactions caused by exposure of the molecule to electrochemical energy must be sufficiently energetic to promote the ECL label to an excited state (either a singlet or a triplet state). Given the high level of skill in the art, the skilled practitioner will be able to predict on the basis of electrochemical and spectroscopic

Appln. No. 09/742,033

Amdt. dated November 24, 2003

Response to Final Office Action of May 30, 2003

properties whether the ECL label has such a state and whether it can be accessed by the application of electrochemical energy. Even in the absence of this information, the skilled practitioner has a wealth of data available on known ECL labels that work by either mechanism.

7. The Term Coreactant Does Not Read on All Compounds.

The Examiner asserts that “it is not possible to determine the limit of compounds that fall within the scope of these claims because the term ‘**coreactant**’ encompasses ‘species which are capable of undergoing a chemical transformation to form said interactive species or said precursor species’, which **would read on all compounds (given an infinite number of chemical transformations).**” (Office Action, p. 12, ¶ 10 (emphasis in original)). In fact, the claims do not allow for an infinite number of transformations but are limited to two: precursor species that are oxidized to form the interactive species (i.e., coreactants that are oxidized to form a reductant) or reduced to form the interactive species (i.e., coreactants that are reduced to form an oxidant). The claims as amended explicitly require that the “coreactant can be oxidized to form a reductant or reduced to form an oxidant.” (See, e.g., Claims 3 and 4). Thus, the claims explicitly exclude compounds which cannot be oxidized to form a reductant or reduced to form an oxidant. Therefore, the Examiner’s assertion that the claim limitation “would read on all compounds” is incorrect.

Accordingly, Applicants respectfully submit that the present claims fully comply with the written description requirement of 35 USC § 112, first paragraph.

B. Claims 3, 4, 10-20, 22 And 26-34 Are Fully Enabled.

Claims 3, 4 and 10-20, 22 and 26-34 are rejected under 35 USC § 112, first paragraph, because the specification “while being enabling for specific metal-tris-terpyridine complexes

Appln. No. 09/742,033

Amdt. dated November 24, 2003

Response to Final Office Action of May 30, 2003

linked tertiary amines disclosed, [purportedly] does not reasonably provide enablement for **any** electrochemiluminescent 'label' linked via **any** 'linker' to **any** 'coreactant'." (Office Action, p. 14, ¶ 11 (emphasis in original)).

Applicants respectfully disagree for the reasons set forth above in Section IV(A), as well as for the following reasons.

Prior to the invention, a wide variety of ECL label/coreactant pairs were known in the art. In particular, a number of systems were known that involved coreactants that were oxidized to form reductants (e.g., oxalate, pyruvate, lactate, malonate, tartrate, citrate and amines, especially tertiary amines) (*see* Specification, p. 13, line 11 - p. 15, line 3) or coreactants that were reduced to form oxidants (e.g., peroxydisulfate) (*see* Specification, p. 15, lines 3-5). Furthermore, it was known to use one or more of these types of coreactants with a variety of different classes of ECL labels including metal containing luminescent complexes (e.g., complexes of Ru, Os, and Re) (*see* Specification, p. 22, line 25 - p. 23, line 12) or luminescent organic compounds including luminescent polyaromatic compounds such as diphenylanthracene (*see* Specification, p. 24, lines 3-23). Applicants' invention stems from the discovery that, for this general class of ECL label/coreactant pairs, linking the coreactant to the label led to a much more efficient generation of ECL than was observed when the two components were separate. The specification (or priority documents that are incorporated by reference) provides several working examples of such ECL label-coreactant conjugates.

Given: (i) the broad disclosure in the specification of suitable ECL labels and coreactants and the significant amount of published data available on working ECL systems employing ECL labels and coreactants as separate components and ii) the broad disclosure in the specification of

Appln. No. 09/742,033

Amdt. dated November 24, 2003

Response to Final Office Action of May 30, 2003

suitable linking chemistries and the high skill in the art of linking groups, one of ordinary skill in the art could, without undue experimentation, select appropriate labels and coreactants (e.g., from label/coreactant pairs that are known to work when used as separate components) and linking chemistries for producing the claimed compounds. Applicants also note that Claims 14-18, 20 and new Claims 35-40 claim compounds that comprise certain classes of amine coreactants and/or organometallic ECL labels that are described in working examples in either the present specification (or in priority documents that are incorporated by reference).

Furthermore, Applicants disagree with the Examiner's analysis of the factors considered in determining whether undue experimentation would be required to practice the invention as set forth in *In Re Wands*, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988), for the following reasons:

1. First, with regard to the second *Wands* factor ("the amount of direction or guidance presented"), the Examiner asserts that "[t]he specification fails to give adequate direction and guidance as to all of the reactions which may be used to transform a compound into a reactive species..." and "the specification teaches limited ECL labels..." (Office Action, p. 15, ¶ 11).

Applicants respectfully traverse. In fact, the claims are limited to two transformations: precursor species that are oxidized to form the interactive species (i.e., coreactants that are oxidized to form a reductant) and those that are reduced to form the interactive species (i.e., coreactants that are reduced to form an oxidant). Coreactants that undergo such transformations are described in the specification (*see* Specification, p. 10, line 1 - p. 15, line 5) and were well known (for systems that use coreactants that are not linked to labels) in the art. Furthermore, the specification also describes and incorporates by reference representative species of

Appln. No. 09/742,033

Amdt. dated November 24, 2003

Response to Final Office Action of May 30, 2003

electrochemiluminescent labels (*see* Specification, p. 3, lines 16-21). Suitable labels described in the specification include a variety of ECL labels other than Os, Ru and Re complexes including organometallic, inorganic and organic labels (*see* Specification, p. 23, line 21 - p. 25, line 2).

The Knight I reference incorporated by reference on page 4 of the specification provides an indication of the state of the art of ECL labels and coreactants at the time the present application was filed. The Knight I reference, however, does not disclose any advantage to be gained by linking an ECL label with a coreactant. The Knight I reference lists many additional ECL labels in Table 1 thereby providing an indication of the knowledge and level of skill in the art at the time of the invention with respect to ECL labels. Knight I describes some ECL mechanisms believed to be common to large classes of ECL labels. (*See*, specifically, reactions 1-4, 7-8 and 13-18 cited therein). Knight I also notes criteria that one skilled in the art could use to select appropriate inorganic ECL labels. (*See* Knight I, p. 883, last paragraph). Preferred ECL labels of the present invention include Ru- and Os-containing complexes. These compounds are advantageous due to their strong electrochemiluminescence. However, Knight I shows that other ECL labels that operate according to similar mechanisms were known in the art, and that criteria necessary for selecting other labels were also known. Given the high level of skill in the art as shown by Knight I, one skilled in the art would be able to select other labels for use in the compounds of the invention and expect the compounds to function in a similar manner.

Thus, one skilled in the art, once in possession of the teachings of the present invention can use the electrochemiluminescent labels and coreactants disclosed in the cited references and specifically delineated in the specification to generate the claimed EL-CR conjugates. There is

Appln. No. 09/742,033

Amdt. dated November 24, 2003

Response to Final Office Action of May 30, 2003

no reasonable basis set forth in the Office Action to support a requirement that the present claims be limited to specific ECL labels disclosed in the working examples of the application.

2. With regard to the third *Wands* factor (“the presence or absence of working examples”), the Examiner alleges that the working examples are “not commensurate in scope with the broad recitations of a ‘coreactant’ or an ‘ECL label’ (e.g., “limited working examples and/or teachings”). (Office Action, p. 15, ¶ 11).

Applicants respectfully traverse. With respect to Claims 14-18, 20 and new Claims 35-40, the claimed compounds are limited, respectively, to compounds comprising certain classes of amine coreactants (Claims 14-18 and 35), or organometallic ECL labels (Claims 20 and 35) that are described in working examples in either the specification of the present application or in priority documents that are incorporated in the specification of the present application by reference. With respect to the other claims, there is no requirement that an applicant provide a working example of his invention. *See In Re Strahilevitz*, 668 F.2d 1229, 1232, 212 USPQ 561, 563 (CCPA 1982). Applicants submit that the “enablement” prong of the first paragraph of 35 USC §112 requires nothing more than objective enablement. Whether this is achieved by illustrative examples or by broad terminology is of no importance. *In Re Marzocchi*, 169 USPQ 367, 369 (CCPA 1971). (*See also*, MPEP § 2164.02).

The subject specification describes the present invention in broad terms and also provides numerous examples of specific preferred embodiments, as well as other teachings either explicitly mentioned in the specification or disclosed in the incorporated references, as discussed above.

Appln. No. 09/742,033

Amdt. dated November 24, 2003

Response to Final Office Action of May 30, 2003

Applicants submit that it is improper to reject claims on the ground that the specification does not support the claims when the terms are no broader than the broadest description of the invention in the specification and there is no reason to challenge the operativeness of the subject matter embraced by the claims. *Ex Parte Altermatt*, 183 USPQ 436, 437-38 (BPAI 1974).

Applicants further submit that enablement is not precluded even where the disclosure requires some experimentation. The test of enablement is not whether any experimentation is necessary, but whether, if experimentation is necessary, is it undue. *In Re Angstadt*, 537 F.2d 498, 504, 190 USPQ 214, 219 (CCPA 1976). (See MPEP § 2164.01). The fact that experimentation may be complex does not necessarily make it undue, if the art typically engages in such experimentation. *In Re Certain Limited-Charge Cell Culture Microcarriers*, 221 USPQ 1165, 1174 (Int'l Trade Comm'n 1983), *aff'd sub nom.*, *MIT. v. A.B. Fortia*, 774 F.2d 1104, 227 USPQ 428 (Fed. Cir. 1985). (See MPEP § 2164.01). In fact, a considerable amount of experimentation is permissible. See *In Re Wands*, 8 USPQ2d 1400, 1403-07 (Fed. Cir. 1988).

Because the relative skill of those in the art is high, the threshold point at which experimentation becomes undue must also be high. Given this, Applicants submit that, based on the instant specification, one skilled in the art would not have to engage in undue experimentation in order to practice the invention as claimed. Thus, the specification provides a description sufficient to enable one of ordinary skill in the art to use the claimed invention without undue experimentation.

3. With regard to the eighth *Wands* factor ("the breadth of the claims"), the Examiner alleges that "[t]he breadth of claims encompasses an indefinitely large number of compounds as it is unclear what is and what is not transformable..." (Office Action, p. 15, ¶ 11).

Appln. No. 09/742,033

Amdt. dated November 24, 2003

Response to Final Office Action of May 30, 2003

It not clear to Applicants how the Examiner arrived at this conclusion. As set forth above, the claims are limited to electrochemiluminescent labels which emit electrochemiluminescence and coreactants that “can be oxidized to form a reductant or reduced to form an oxidant.” Contrary to the Examiner’s assertions, these limitations do not read on “all compounds.” Moreover, a person of ordinary skill in the art would readily recognize how to pre-select compounds (based on the disclosure in the specification, the incorporated references and the high level of skill in the art) and how test compounds and coreactants based on routine screening available to a skilled artisan at the time the subject application was filed.

Moreover, the specification need not provide examples or a specific description of embodiments for the entire scope of the invention. Applicants respectfully submit that additional examples of the complexes of ECL labels linked to coreactants are not necessary if the description of the invention itself is sufficient to permit those skilled in the art to make and use the invention. (MPEP § 2164). A patent does not teach, and preferably omits, what is well known in the art. *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 231 USPQ 81, 94 (Fed. Cir. 1986), *cert. denied*, 480 U.S. 947 (1987). (See MPEP § 2164.01).

4. With regard to the fifth *Wands* factor (“the state of the prior art”), the Examiner alleges that “[t]he state of the art is such that a number of compounds that might be useful as coreactants have been prepared and even linked to ECL labels.” (Office Action, p. 16, ¶ 11).

The Examiner’s statement is indicative that the state of the prior art is high. However, Applicants are unaware of any such compounds disclosed in the prior art. It is unclear how this statement supports an enablement rejection and, in fact, seems to argue against it by recognizing that there is a high level of skill in the prior art.

Appln. No. 09/742,033

Amdt. dated November 24, 2003

Response to Final Office Action of May 30, 2003

5. With regard to the seventh *Wands* factor (“the predictability or unpredictability of the art”), the Examiner states that “[t]he art is inherently unpredictable because it is not possible to know *a priori*, which coreactant ... will be transformable when linked to an ECL label and actually function as predicted with an undefined series of undisclosed ECL labels.” (Office Action, p. 16, ¶ 11).

Applicants respectfully traverse. It is unclear how the Examiner reaches this conclusion. As has been described in detail above, numerous ECL label/coreactant pairs were described in the specification or known in the art. Many of these use coreactants that meet the limitation of the amended claims that the “coreactant can be oxidized to form a reductant or reduced to form an oxidant.” As described above, many of these were believed in the art to work by similar mechanisms. Given this state of the art combined with the disclosure of the present invention, Applicants urge that those of ordinary skill in the art would have been able to pick, *a priori*, suitable label/coreactant pairs for use in the claimed compounds based on the known behavior of materials used in ECL reactions employing separate label and coreactant components. The Examiner provides no evidence that other labels and coreactants, in particular those sharing a common mechanism, would be expected to behave differently. The Examiner also provides no evidence that the compounds would be especially sensitive to the nature of the linking group used to link the coreactant and label outside of factors such as length that could easily be optimized without undue experimentation.

Even assuming, for the sake of argument, that not all ECL label/coreactant pairs work when linked together, the screening of labels and coreactants for suitable pairs is not undue

Appln. No. 09/742,033

Amdt. dated November 24, 2003

Response to Final Office Action of May 30, 2003

experimentation given the body of routine experimentation methods which easily allow a skilled artisan to test if the desired result is achieved.

Applicants also respectfully disagree with the Examiner's use of the Knight II reference to argue that a skilled artisan willing to find a suitable pair of a label and co-reactant would not be able to achieve it without undue experimentation. (*See* Office Action, p. 19, ¶ 14). The successful examples of ECL reported in Knight II are evidence in support of Applicants' assertions and provide strong evidence of the availability of numerous labels and coreactants which could be used by a skilled practitioner to create the claimed compounds.

The Examiner also relies on the statement in Knight II that "[m]any tertiary amine compounds produce intense emission whereas other structurally related similar compounds produce virtually no ECL emission" (Office Action, p. 19, ¶ 14) to support his argument. Applicants urge that the quote has been misapplied. After making that statement, Knight II goes on to review the literature on amine coreactants and to form conclusions tying the activity of amine coreactants to certain structural features (Knight II, p. 105R, col. 2) showing that, contrary to the Examiner's assertions, there is predictability in the selection of amine coreactants.

Finally, the present claims are limited to coreactants and ECL labels having the required properties and thus exclude inoperable subject matter.

Accordingly, Applicants respectfully request the withdrawal of the enablement rejection of Claims 3, 4, 10-20, 22 and 26-34 under 35 USC § 112, first paragraph.

C. Claims 3, 4, 9-20, 22 And 26-34 Are Definite.

Claims 3, 4, 9-20, 22 and 26-34 also are rejected under 35 USC § 112, second paragraph, as purportedly being "indefinite for failing to particularly point out and distinctly claim the

Appln. No. 09/742,033

Amdt. dated November 24, 2003

Response to Final Office Action of May 30, 2003

subject matter which applicant regards as the invention.” (Office Action, p. 22, ¶ 15). In particular, the Examiner asserts “the claim is vague and indefinite because it is not possible to determine which components are, or are not, coreactants and what processes or transformations are being conducted.” (Office Action, p. 22, ¶ 15(A)). Applicants respectfully disagree.

Applicants urge that the definiteness of claim language must be analyzed, not in a vacuum, but in light of: (1) the content of the particular application disclosure, (2) the teachings of the prior art, and (3) the claim interpretation that would be given by one possessing the ordinary level of skill in the pertinent art at the time the invention was made. (MPEP § 2173.02). Given the detailed description in the specification of ECL coreactants (through examples, functional definition, lists of suitable coreactants and references to appropriate literature), the substantial body of literature that was available on ECL coreactants at the time of the invention, and the high level of skill in the art, Applicants urge that one of ordinary skill in the art would readily understand the meaning of the term “coreactant” when properly construed in view of the specification and what is known in the art. Thus, the claims fully meet the requirements of 35 USC § 112, second paragraph.

With respect to the Examiner’s statement that “conceivably any compound could fall within Applicants [sic] functional language given an infinite number of chemical transformations to change the ‘precursor species’ into the ‘interactive species’” (Office Action, p. 25, ¶ 16), Applicants note that the claims are, in fact, limited to coreactants that undergo one of only two transformations, i.e., coreactants that are “oxidized to form a reductant, or reduced to form an oxidant.” This chemical property defines a narrow subgenus of compounds and an artisan skilled in the art of electrochemistry would readily recognize which compounds belong to the

Appln. No. 09/742,033

Amdt. dated November 24, 2003

Response to Final Office Action of May 30, 2003

subgenus, or would know how to determine which compounds belong to a claimed subgenus.

The specification elaborates on the preferred embodiments of such coreactants and gives specific structural details of the preferred coreactants (*see, e.g.,* Specification, p. 13, line 1 - p. 15, line 5), *e.g.* “Amines which are advantageously utilized in the present invention are aliphatic amines, such as ...” (Specification, p. 13, lines 11-12) and “other suitable [...] are oxalate or other organic acid radicals such as pyruvate, lactate, tartrate, and citrate” (Specification, p. 15, lines 1-3).

With respect to the Examiner’s objection to the claims as defining material solely on a functional basis, Applicants note that there is no requirement that a claimed compound be described through use of a structure and that compounds may be claimed by a combination of physical and chemical characteristics. (*See* MPEP § 2173.05(t)). Applicants further note that Claims 13-18 and new Claims 35-40 explicitly specify structural characteristics of the coreactant.

With respect to the Examiner’s specific objection to Claim 22, Applicants note that Claim 22 has been canceled for reasons other than those related to patentability, and, therefore, this argument is moot with respect to that claim.

In light of the above, Applicants respectfully request withdrawal of the rejection of Claims 3, 4, 9-20, and 26-34 based on 35 USC § 112, second paragraph.

**D. Claims 3-4, 10, 12-13, 18-20, 22, 26-27 And 29-34 Are Patentable
Over Liang et al.**

Claims 3-4, 10, 12-13, 18-20, 22, 26-27, and 29-34 are rejected as being anticipated by Liang. (Office Action, pp. 26-27, ¶¶ 17-18). Applicants disagree.

Appln. No. 09/742,033

Amdt. dated November 24, 2003

Response to Final Office Action of May 30, 2003

Applicants urge that Liang, which was not published until 1996, is not prior art under 35 USC § 102(a). The present specification claims priority to June 7, 1995, the filing date of parent application Serial No. 08/485,419 (now U.S. Patent No. 5,643,713 to Liang et al. issued July 1, 1997) (“the Liang ‘713 patent”) and, therefore, Claims 3-4, 10, 12-13, 18-20, 22, 26-27 and 29-34 are entitled to a priority date of June 7, 1995, as discussed in Section III, *supra*.

Therefore, the rejection of Claims 3-4, 10, 12-13, 18-20, 22, 26-27 and 29-34 under 35 USC § 102(a) as being anticipated by Liang should be withdrawn.

E. Claims 3-4, 11, 13 and 14 Are Patentable Over Faulkner.

The basis of the Examiner’s rejection of Claims 3-4, 11, 13, and 14 as being anticipated by Faulkner is a compound of Itaya and Toshima (an electrochemiluminescent label (anthracene acceptor) linked via a methylene chain to a coreactant (N,N-dimethylaniline donor)) referenced in Faulkner. (See Office Action, p. 28, ¶ 19).

“A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.” *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). “The identical invention must be shown in as complete detail as is contained in the...claim”. *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989). (See MPEP § 2131).

Applicants submit that each and every element set forth in the claims at issue is not expressly found in Faulkner. First, the Examiner incorrectly characterizes anthracene and dimethylaniline as separate label and coreactant components. Faulkner states that the emission comes from an intramolecular exciplex comprising both anthracene and dimethylaniline. As

Appln. No. 09/742,033

Amdt. dated November 24, 2003

Response to Final Office Action of May 30, 2003

both components are involved in the emission, they make up a single ECL label. There is no separate ECL coreactant present.

Even assuming, for the sake of argument, that the dimethylaniline can be described as a separate coreactant, the compound of Itaya and Toshima would be expected to require oxidation of the luminophore and concurrent reduction of the dimethylaniline moiety to provide a strong reductant, not a strong oxidant (*see* the mechanism on p. 507 of Faulkner). By contrast, the coreactants of amended Claims 3 and 4 require a coreactant that undergoes oxidation to form a reductant or reduction to form an oxidant. (*See* Claims 3 and 4). This is a chemical property (and not the intended use; the limitation excludes compounds that do not exhibit the claimed property) of the coreactant of the present invention which allows for the formation on an oxidizing electrode of both an oxidized ECL label and a reduced coreactant (or alternatively, the formation at a reducing electrode of both a reduced ECL label and an oxidized coreactant). The cited reference does not disclose a coreactant which can undergo oxidation to form a reductant or reduction to form an oxidant.

The ability of a compound to be reduced by oxidizing potential and oxidized by reducing potential is not a property of N,N-dimethylaniline, as described in Faulkner. The Examiner's contention that "it does not rule out the possibility that the compound could also undergo the mechanism claimed by Applicant" (Office Action, p. 29, ¶ 20) is unsupported by evidence. Applicants are unaware of any scientific literature which postulates or proves this point. Scientific literature exists, in fact, that refutes the Examiner's position. Knight II notes that aniline and a variety of substituted anilines do not work as coreactants for generating ECL from Ru(bpy)₃. (*See* Knight II, p. 104R, col. 1). Furthermore, there does not appear to be any

Appln. No. 09/742,033

Amdt. dated November 24, 2003

Response to Final Office Action of May 30, 2003

reasonable basis for asserting that the compounds disclosed in the cited reference inherently have this characteristic either.

Moreover, the compounds of Faulkner do not "inherently" fall within the scope of the claims. From the description in Faulkner, in fact, is clear that the compound undergoes reduction under reducing potential which provides evidence to the contrary. (*See* Faulkner, p. 507). In order to make a rejection based on "inherency," the Examiner "must provide a basis in fact and/or technical reasoning to reasonably support the determination that the purportedly inherent characteristic necessarily flows from the teachings of the prior art." *Ex Parte Levy*, 17 USPQ 2d 1461, 1464 (BPAI 1990). The fact that a prior art article may inherently have the characteristics of the claimed article is not sufficient. *Ex Parte Skinner*, 2 USPQ 2d 1788, 1789 (BPAI 1986). Inherency must be a necessary result and not merely a possible result. *In Re Oelrich*, 666 F.2d 578, 581-82, 212 USPQ 2d 323, 326 (CCPA 1981); *Ex Parte Keith*, 154 USPQ 320 (BPAI 1966). To establish inherency, the extrinsic evidence "must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill." *In Re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999) (citing *Continental Can Co. v. Monsanto Co.*, 20 USPQ2d 1726, 1749 (Fed. Cir. 1991)). (*See*, particularly, MPEP § 2112).

Accordingly, Claims 3-4, 11, 13 and 14 are not anticipated by Faulkner, and the Examiner's rejection under 35 USC § 102(b) should be withdrawn.

Appln. No. 09/742,033

Amdt. dated November 24, 2003

Response to Final Office Action of May 30, 2003

**F. Claims 3-4, 10-14, 19-20, 22, 26-27 And 29-34 Are Patentable
Over Massey WO 87/06706**

Claims 3-4, 10-14, 19-20, 22, 26-27 and 29-34 are rejected under 35 USC §102(b) as purportedly being anticipated by Massey WO 87/06707. (Office Action, pp. 31-33, ¶¶ 21-22). Applicants respectfully disagree.

The Examiner's argument is based on an unwarranted interpretation of certain binding reagents (e.g., digoxigenin and theophylline) as being "capable after chemical transformation of participating in an ECL reaction." (Office Action, p. 32, ¶ 22). The Examiner provides no factual support for his assertion that digoxigenin and theophylline can be transformed into coreactants. Even more specifically, there is no evidence to support any assertion that digoxigenin and theophylline undergo oxidation to form a reductant or reduction to form an oxidant. Finally, there is no evidence that digoxigenin and theophylline can or do interact with the ECL label to produce electrochemiluminescence. Applicants note that digoxigenin and theophylline are used in Massey WO 87/06706 to bind another entity such as an antibody with which it forms a complex. There is no indication in Massey that digoxigenin and theophylline play a role in the actual emission of ECL.

Furthermore, the disclosure of Ru(bpy)₃ linked to Ru(bpy)₃ also fails to anticipate the claimed invention. (See Massey WO 87/06706, p. 144). As is indicated by the reaction mechanism drawn by the Examiner, Ru(II)(bpy)₃ is not oxidized to produce a reductant or reduced to produce an oxidant.

"A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). "The identical invention

Appln. No. 09/742,033

Amdt. dated November 24, 2003

Response to Final Office Action of May 30, 2003

must be shown in as complete detail as is contained in the...claim". *Richardson v. Suzuki Motor Co.*, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989). (See MPEP § 2131).

Accordingly, the rejection of Claims 3-4, 10-14, 19-20, 22, 26-27 and 29-34 as anticipated by Massey WO/ 87/06706 under 35 USC § 102(b) is inappropriate and should be withdrawn.

**G. Claims 3-4, 10-14, 19-20, 22, 26-27 and 29-34 Are Patentable
Over The Massey '581 Patent Under 35 USC § 102(e).**

Claims 3-4, 10-14, 19-20, 22, 26-27 and 29-34 are also rejected under 35 USC § 102(e) as purportedly being anticipated by the Massey '581 patent because the patent discloses "electrochemiluminescent labels with a coordinated Re atom linked to numerous compounds 'B' where B can be peptides, nucleic acids, polysaccharides, alkaloids, steroids, vitamins, amino acids or non-biological polymers" and "teaches amines linked to ECL labels." (Office Action, pp. 33-34, ¶ 23). Applicants respectfully disagree.

The Massey '581 patent does not anticipate the claimed invention because it does not disclose "B" compounds as a "coreactant" or a coreactant precursor species. More specifically, there is no reasonable basis to support the assertion that "B" of the Massey '581 patent can "undergo oxidation to form a reductant or reduction to form an oxidant." With respect to Claim 14, the Examiner also does not elucidate where the Massey '581 patent shows the linkage of an ECL label to a tertiary amine.

In order to have a valid rejection under 35 USC § 102(e), all the elements of the rejected claims must be disclosed in the cited reference. To the extent that a coreactant linked to an ECL label is not disclosed, the Massey '581 patent cannot anticipate the claims. Accordingly, this rejection is inappropriate and should be withdrawn.

Appln. No. 09/742,033

Amdt. dated November 24, 2003

Response to Final Office Action of May 30, 2003

**H. Claims 3-4, 10-14, 19-20, 22, 26-27 and 29-34 Are Patentable
Over The Massey '581 Patent Under 35 USC § 102(f).**

Claims 3-4, 10-14, 19-20, 22, 26-27 and 29-34 are rejected under 35 USC § 102(f) as being unpatentable over the Massey '581 patent because "[t]he claimed subject matter appears to have been invented by Massey et al." and because the claims "are directed to an invention not patentably distinct from claims 1-6 and 20 of commonly assigned 5,591,581." (Office Action, p. 35, ¶ 25). Applicants respectfully traverse.

"It is axiomatic that for prior art to anticipate under § 102 it has to meet every element of the claimed invention." *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 231 USPQ 81, 90 (CAFC 1986), *cert. denied*, 480 U.S. 947 (1987). Section 102(f) upon which the Examiner relies is one type of "anticipation," and, therefore, requires that the purported prior invention contain all the elements of the claimed invention.

As discussed in Section IV(G), *supra*, the Massey '581 patent does not anticipate the claimed invention because: (i) it does not disclose "B" compounds as a "coreactant" or a coreactant precursor species; (ii) there is no reasonable basis to support a contention that "B" of the Massey '581 patent can "undergo oxidation to form a reductant or reduction to form an oxidant" as do the coreactants of the claimed invention; and (iii) with respect to Claim 14, the Examiner does not elucidate where the Massey '581 patent discloses the linkage of an ECL label to a coreactant.

Since the Massey '581 patent does not anticipate Claims 3-4, 10-14, 19-20, 22, 26-27 and 29-34, rejection under 35 USC § 102(f) is inappropriate and should be withdrawn.

Appln. No. 09/742,033

Amdt. dated November 24, 2003

Response to Final Office Action of May 30, 2003

**I. Claims 3-4, 9-20, 22 And 26-34 Are Not Obvious Over Knight I
In View Of Faulkner.**

Claims 3-4, 9-20, 22 and 26-34 are rejected as being obvious over Knight I in view of Faulkner. (Office Action, pp. 37-39, ¶¶ 27-28). Applicants urge that the present invention is not obvious over the disclosure of Knight I alone or in combination with Faulkner.

The Examiner admits that Knight I “does not teach the advantage of linking an EL with a CR.” (Office Action, p. 37, ¶ 27). As discussed above in Section IV(E), the cited compound in Faulkner does not comprise a separate label and coreactant, but rather only the label, the observed emission being derived from an exciplex involving both the anthracene and dimethylaniline ring structures. Therefore, the Examiner’s suggested combination does not result in the claimed compound.

Even assuming, for the sake of argument, that the dimethylaniline moiety can be described as a coreactant, Applicants urge that Faulkner does not compensate for the deficiencies of Knight I. There is no evidence of record to support an assertion that dimethylaniline can act as a coreactant that undergoes oxidation to form a reductant or reduction to form an oxidant. (See Section IV(E), *supra*). Furthermore, neither Knight I nor Faulkner predict the unexpectedly high ECL efficiency that was obtained by linking such coreactants to ECL labels, nor do they provide any motivation for carrying out such a linkage.

The suggestion to combine elements must come from a reference cited and not from an applicant’s disclosure. See *In Re Dow Chemical Co.*, 837 F.2d 469, 473, 5 USPQ2d 1529, 1531 (Fed. Cir. 1988). To establish prima facie obviousness based upon a combination of references, the Examiner is required to demonstrate that the prior art provides “a reason, suggestion, or

Appln. No. 09/742,033

Amdt. dated November 24, 2003

Response to Final Office Action of May 30, 2003

motivation to lead an inventor to combine those references.” *Pro-Mold & Tool Co. v. Great*

Lakes Plastics Inc., 75 F.3d 1568, 1573, 37 USPQ2d 1626, 1629 (Fed. Cir. 1996).

[E]vidence of a suggestion, teaching, or motivation to combine may flow from the prior art references themselves, the knowledge of one of ordinary skill in the art, or, in some cases, from nature of the problem to be solved. ... The range of sources available, however, does not diminish the requirements for actual evidence. That is, the showing must be clear and particular.

In re Dembiczak, 175 F.3d 994, 999, 50 USPQ2d 1614, 1617 (Fed. Cir. 1999) (Citations omitted). There is no teaching or suggestion in the cited references which would motivate one of ordinary skill in the art to practice the presently claimed invention.

Accordingly, the rejection of Claims 3-4, 9-17, 19 and 21-22 under 35 USC § 103(a) over Knight I in view of Faulkner should be withdrawn.

J. The “Obviousness-Type Double Patenting” Rejection Over Claims 1-6 And 19-20 Of The Massey ‘581 Patent Is Unwarranted.

The rejection of Claims 3-4, 9-20, 22 and 26-34 under the judicially created doctrine of obviousness-type double patenting over claims 1-6 and 19-20 of the commonly assigned Massey ‘581 patent is believed to be unwarranted. Applicants have previously addressed the issue of obviousness-type double patenting with respect to claims 1-6 of the commonly assigned Liang ‘713 patent.

Applicants respectfully traverse with respect to the double-patenting rejection over the Massey ‘581 patent. The Massey ‘581 patent does not disclose the presently claimed subject matter as discussed above in Section IV(G).

Furthermore, the focus of any double patenting analysis is on the claims in the patents or patent applications involved. (MPEP §804). The present claims relate to compounds comprising

Appln. No. 09/742,033

Amdt. dated November 24, 2003

Response to Final Office Action of May 30, 2003

ECL labels linked to coreactants, wherein the coreactant undergoes oxidation to form a reductant or reduction to form an oxidant. The claims of the Massey '581 patent do not teach or suggest the presently claimed subject matter. The MPEP clearly states:

One significant difference [between a double patenting rejection and a rejection based on prior art] is that a double patenting rejection must rely on a comparison with the claims in an issued or to be issued patent, whereas an obviousness rejection based on the same patent under 35 U.S.C. 102(e)/103(a) relies on a comparison with what is disclosed (whether or not claimed) in the same issued or to be issued patent. In a 35 U.S.C. 102(e)/103(a) rejection over a prior art patent, the reference patent is available for all that it fairly discloses to one of ordinary skill in the art, regardless of what is claimed. *In re Bowers*, 359 F.2d 886, 149 USPQ 570 (CCPA 1966).

(MPEP § 804 (III), p. 800-29).

Thus, it is the claims of the issued patent that must be analyzed, not the entire specification. Applicants respectfully submit that a claim-by-claim analysis does not support the Examiner's assertion of non-statutory obviousness-type double patenting. Accordingly, Applicants urge that the rejection of Claims 3-4, 9-20, 22 and 26-34 under the judicially created doctrine of obviousness-type double patenting over the claims of the Massey '581 patent is improper and its withdrawal is respectfully requested.

With respect to the Liang '713 patent, Applicants have previously advised during the prosecution of the parent application that they are willing to provide a terminal disclaimer disclaiming the remaining term of the present application over the Liang '713 patent without admitting obviousness over the cited patent if doing so will result in the allowance of the application.

Appln. No. 09-742,033

Amdt. dated November 24, 2003

Response to Final Office Action of May 30, 2003

K. Claims 3-4, 9-20, 22 and 26-34 Are Directed to Statutory Subject Matter.

Claims 3-4, 9-20, 22 and 26-34 are rejected under 35 USC § 101 as purportedly being directed to non-statutory subject matter. (Office Action, p. 42, ¶ 32).

Applicants respectfully traverse. The Examiner misinterprets a chemical property of the co-reactant described as “coreactant undergoes oxidation to form a reductant or reduction to form an oxidant” for a statement of intended use. (See Claim 3 before present amendment). The term is a claim limitation which requires that the compound have the recited property or characteristic and thus excludes compounds not having such property or characteristic. Thus, the limitation is not an “intended use” limitation. However, to further prosecution of the application, Applicants have amended Claims 3 and 4 to further emphasize that the limitation is a required property or characteristic of the claimed compounds.

L. The Subject Matter of Claims 3-4, 9-20, 22 and 26-34 Is Fully Supported by the Specification.

Claims 3-4, 9-20, 22 and 26-34 are rejected under 35 USC § 112, first paragraph, as containing new subject matter not supported by the specification. In particular, the Examiner asserts that Applicants are not in possession of the “smaller amended subgenus” of Claims 3 and 4 because:

... the specification explicitly states that the scope of the invention is not to be bound by a theoretical explanation of the reaction mechanism (see specification page 11, lines 1-2) and Applicants [sic] current amendments would fall within the scope of that statement because the reduction and/or oxidation of the coreactant defines Applicants [sic] postulated mechanism by which the ECL reaction occurs (see specification, pages 10-11).

(Office Action, p. 43, ¶ 33). Applicants respectfully disagree.

Appln. No. 09/742,033

Amdt. dated November 24, 2003

Response to Final Office Action of May 30, 2003

The Examiner misinterprets a chemical property of the co-reactant described as “coreactant undergoes oxidation to form a reductant or reduction to form an oxidant” for a statement of intended use, or a mechanism of action. Contrary to the examiner’s contention, Claims 3 and 4, as amended, specify that suitable coreactants must have the chemical property that they can be “oxidized to form a reductant or reduced to form an oxidant.” This chemical property defines a narrow subgenus of compounds and an artisan skilled in the art of electrochemistry would readily recognize which compounds belong to this subgenus, or would know how to determine which compounds belong to the claimed subgenus. The fact that Applicants do not wish to be bound by the theoretical explanation of the ECL reaction is immaterial, where the invention is described in sufficient detail of structural and physico-chemical properties. (*See* Section IV(A), *supra*).

The test for written description under 35 USC §112, first paragraph, is whether the originally filed specification reasonably conveys to a person having ordinary skill that Applicants had possession of the subject matter later claimed. *In re Kaslow*, 217 USPQ 1089, 1096 (Fed. Cir. 1983). (*See also*, MPEP § 2163.02). Applicants clearly invented what is claimed in the subject specification.

Claims 28 and 29 are additionally specifically rejected under 35 USC § 112, first paragraph, as containing new subject matter because there purportedly is no support in the specification for (1) “a combination thereof” of the linkers listed in Claim 28 and (2) “combinations thereof” of the linkers listed in Claim 29. (Office Action, p. 43, ¶ 33). Applicants respectfully disagree.

Appln. No. 09/742,033

Amdt. dated November 24, 2003

Response to Final Office Action of May 30, 2003

The specification provides explicit details of linking chemistries and structural details of a number of linkers. (*See* Section IV(A), *supra*). Based on the disclosure of the specification and the high state of relevant art, a skilled artisan will readily recognize how to combine disclosed linkers.

Consequently, the rejection of Claims 3-4, 9-20, 22 and 26-34 under 35 USC § 112, first paragraph, as containing new subject matter not supported by the specification is improper and should be withdrawn.

**M. **Claims 3-4, 9-20, 22 and 26-34 Are Not
Obvious Over Knight II In View Of Faulkner.****

Claims 3-4, 9-20, 22 and 26-34 are rejected as being obvious over Knight II in view of Faulkner. (Office Action, pp. 46-47, ¶ 37). Applicants respectfully traverse.

The present invention claims priority to U.S.S.N. 08/484,766 filed June 7, 1995. The Knight II reference was published in November 1996 subsequent to the priority date of the subject application. Therefore, Knight II is not available as prior art. Even assuming, for the sake of argument, that Knight II was available as prior art, the obviousness rejection is improper for the same reasons that the claims are not obvious over Knight I in view of Faulkner. (*See* Section IV (H)). Thus, the rejection is improper and should be withdrawn.

II. **Conclusion**

In view of the amendments and remarks submitted herein, reconsideration and withdrawal of the rejections to Claims 3, 4, 9-20, and 26-34 pending in this application is earnestly solicited, together with favorable consideration of new Claims 35-40, and prompt issuance of a Notice of Allowance.

Appln. No. 09/742,033

Amdt. dated November 24, 2003

Response to Final Office Action of May 30, 2003

Applicants submit that the instant application is in condition for allowance, the early notification of which is respectfully requested.

Respectfully submitted,

KRAMER LEVIN NAFTALIS & FRANKEL LLP

919 Third Avenue

New York, New York 10022

Tel: (212) 715-9100

Fax: (212) 715-8000

Attorneys for Applicants

By: Mary W. Richardson
Barry Evans, Reg. No. 22,802
Mary W. Richardson, Reg. No. 48,320